300.1012

UNITED STATES PATENT & TRADEMARK OFFICE

Re:	Application of:	Xiu Xiu Cheng, et al.
	Serial No.:	09/705,625
	Filed:	November 3, 2000
	For:	**Methods for Treating Diabetes Via Administration Of Controlled Release Metformin**
	Examiner: T. Page	Art Unit: 1615

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

November 25, 2003

Communication accompanying the

Statement of Substance of Interview Under 37 CFR §1.133

S i r:

Upon review of the prosecution history of the present application during the preparation of this response, it was noted that complete copies of the PTO-1449 forms submitted with the Information Disclosure Statements of September 17, 2001 and February 28, 2003 were not initialed and returned to the undersigned. As certain references were disassociated from the file, Applicants again include herewith the Information Disclosure Statements of September 17, 2001 and February 28, 2003, along with the PTO-1449 forms and the references cited therein. The Examiner is requested to consider all of the references herein and return the initialed PTO-1449 forms to the undersigned.

According to currently recommended Patent Office policy the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

An early and favorable action is earnestly solicited.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____

Clifford M. Davidson
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S i r:

Reconsideration of the present application in view of the following remarks is respectfully requested.

I. INTRODUCTORY COMMENTS

The undersigned gratefully acknowledges the courtesies extended by Examiner Page to the undersigned and Ted Whitlock, Esq. during the Interview conducted at the USPTO on November 20, 2003.

The Interview conducted on November 20, 2003 also included a separate discussion of applicant's copending Application Serial No. 09/705,630. A separate Amendment Under 37 CFR§1.111 and Statement of Substance of Interview Under 37 CFR §1.133 have been submitted for Serial No. 09/705,630.

II. REMARKS

During the Interview, the undersigned discussed the Office Action dated July 14, 2003 and applicants' response dated October 14, 2003.

In that Office Action, the Examiner had indicated that claim 25 would be allowable if rewritten in independent form. By virtue of the amendment the subject matter of claim 25 was rewritten in independent form, without prejudice to applicants pursuing remaining subject matter in continuation applications.

It was agreed that the claims were allowable over the prior art previously relied upon by the Examiner.

Nevertheless, during the course of the interview, the rejection of claims 1, 4-5, 7-15, 18-24, and 26-31 under 35 U.S.C. 103(a) over Lewis et al. in combination with Chiao and Drug Facts and Comparisons or Moeckel et al. in combination with Chiao and Drug Facts and Comparisons; and claims 1, 4-5, 7-15, 18-24, and 26-31 under 35 U.S.C. 103(a) over Cheng et al. in view of Drug Facts and Comparisons, was discussed.

During the interview, it was pointed out to Supervisory Examiner Page that Lewis et al. is directed to a combination product (insulin sensitizer plus another antidiabetes agent, which could be metformin), wherein it is stated that one or both of the active agents could be in modified release form. It was noted that Lewis et al. provide no in-vivo data whatsoever, and in fact do not mention any possible pharmacokinetic parameters which their formulations should meet. As stated in the last Office Action, Lewis et al. "do not teach the exact release profile(s) of the instant claims." It was further argued that Chaio and Drug Facts and Comparisons do not overcome the deficiencies of Lewis et al. with respect to the particular T_{max} range set forth in the

claims. Supervisory Examiner Page agreed that the claimed T_{max} range was patentable over the combination of Lewis, Chiao and Drug Facts and Comparisons.

During the interview, it was pointed out to Supervisory Examiner Page that the Moeckel et al. reference, while directed to retarded tablets containing metformin, does not suggest that the formulations described therein are useful for once-a-day administration. Instead, Moeckel et al. state that the retarded tablets of their invention "release metformin in a controlled manner over a time period of 0.5 – 10 hours preferably over 4 hours (FIG. 1)." (Column 5, lines 30-32). It was noted that Moeckel et al. provide no in-vivo data whatsoever, and in fact do not mention any possible pharmacokinetic parameters which their formulations should meet. As stated in the last Office Action, Moeckel et al. "do not teach the exact release profile(s) of the instant claims." It was further argued that Chaio and Drug Facts and Comparisons do not overcome the deficiencies of Lewis et al. with respect to the particular T_{max} range set forth in the claims. In response, Supervisory Examiner Page agreed that the claimed T_{max} range was patentable over the combination of Moeckel, Chiao and Drug Facts and Comparisons.

During the Interview, with respect to the rejection based on the combination of Cheng, et al. and Drug Facts and Comparisons, the T_{max} data presented in the Cheng, et al. reference was discussed in detail, and the Examiner's attention was directed to the discussion provided in applicants' responsive papers of February 2003 with respect to the T_{max} information presented in the '859 patent. It was pointed out to Supervisory Examiner Page that the '859 patent was the U.S. priority application to the Cheng, et al. reference. The relationship of the claimed T_{max} range of claim 1 (5.5 – 7.5 hours) when the dosage forms of the invention are administered after dinner was discussed with respect to providing the highest level of the drug in the blood at night (e.g., when gluconeogenesis is greatest; see the specification at pages 13-14). Supervisory Examiner Page considered the closest prior art to teach a T_{max} of 8 hours (the Cheng, et al. reference).

Supervisory Examiner Page agreed that the "applicants' arguments regarding the Tmax are persuasive that the method claims distinguish over the prior art" and indicated that the claims of record are allowable. (See the Examiner Interview Summary Record of November 20, 2003).

During the Interview, the rejection of claims 1, 4-5, 7-15, and 18-31 for obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,099,859; claims 1-39 of U.S. Patent No. 6,284,275; and claims 1-4 of U.S. Patent No. of U.S. Patent No. 6,099,862 were discussed. In addition the provisional rejection of claims 1, 4-5, 7-15, and 18-31 over claims 1-29 of copending Application No. 09/726,193 was discussed.

During the interview, the Examiner indicated that the above-mentioned obviousness-type double patenting rejections would not be maintained as per the policy of the USPTO and *In re Schneller*, 158 USPQ 210 (CCPA 1968).

According to currently recommended Patent Office policy the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

An early and favorable action is earnestly solicited.

Respectfully submitted,
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FORM PTO-1083

Docket No.: 300.1012
Date: November 25, 2003

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

In re application: Xiu Xiu Cheng, et al.
Serial No.: 09/705,625
Filed: November 3, 2000
For: **Methods For Treating Diabetes Via Administration Of Controlled Release Metformin**

S i r:

Transmitted herewith is an **Statement of Substance of Interview** in the above-identified application.

[ ] Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.
[ ] Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.
[X] No fee for additional claims is required.
[ ] A filing fee for additional claims calculated as shown below, is required:

	(Col. 1)	(Col. 2)		SMALL ENTITY		OR	LARGE ENTITY	
FOR:	REMAINING AFTER AMENDMENT	HIGHEST PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	FEE		RATE	FEE
TOTAL CLAIMS	* Minus** =	0		x $ 9	$		x $ 18	$
INDEP. CLAIMS	* Minus*** =	0		x $ 42	$		x $ 84	$
[ ] FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+ $140	$		+ $280	$
				TOTAL:	$	OR	TOTAL:	$

* If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[X] Also transmitted herewith are:
[ ] Petition for extension under 37 C.F.R. 1.136
[X] Other: **Communication and Copies of previously submitted Information Disclosure Statements of September 17, 2001 and February 28, 2003 including PTO-1449 forms, and References Cited therein.**

[ ] Check(s) in the amount of **$0.00** is/are attached to cover:
[ ] Filing fee for additional claims under 37 C.F.R. 1.16
[ ] Petition fee for extension under 37 C.F.R. 1.136
[ ] Other:

[X] The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.

[X] Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
[X] Any patent application processing fees under 37 C.F.R. 1.17.
[X] Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with sufficient postage to the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on
November 25, 2003
DAVIDSON, DAVIDSON & KAPPEL, LLC
BY: